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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/723,459	11/28/00	MORELLI-ABRAMS I	680.0041USU

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EXAMINER	
OSTRUP,C	
ART UNIT	PAPER NUMBER
1619	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/723,459	Applicant(s) MORELLI-ABRAMS ET AL.	
	Examiner Clinton Ostrup	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-25 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving, promoting, improving, enhancing, reducing, restoring, and minimizing problems associated with skin appearance, it does not reasonably provide enablement for preventing skin ailments. Claims 15-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating/ameliorating skin ailments, it does not reasonably provide enablement for preventing them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The burden of enabling the prevention of skin ailments (i.e. the need for additional testing) would be greater than that of enabling a treatment for the specific skin ailments. In the instant case, the specification does not

provide guidance as to how one skilled in the art would go about preventing ailments on skin or how the skin could be kept from being susceptible to these ailments. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing extrinsic and intrinsic aging of the skin. Specifically, it is highly unlikely, and the Office would require experimental evidence to a claim such as that of claim 18, which claims to prevent the chronological aging of skin. The specification fails to enable one of ordinary skill in the art to practice and use the methods of instant claims 14-21.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 8, 11-12, 20-21, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and confusing because the terminology "in from about." The word "in" is not necessary in this claim and should be deleted

to add clarity to the claim or in the alternative, applicant may add "an amount" after the word "in" to clarify this claim.

Claims 2-3, 11-12, 20-21, and 24 are vague and indefinite because it is it is unclear what percentage of crape myrtle is in the extract. A pure oil extract would be much more concentrated that an aqueous extract and therefore the weight percentages as claimed are vague and indefinite because the extract's concentration is not defined.

Claim 8 is vague and confusing because "colosic acid" is not a term commonly used in the art. It appears claim 8 should have the term "colosolic acid."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 8, 10, and 22-23, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO **JP 07138135A** based on the Derwent Abstract and the English translation of the Abstract and Disclosure provided by the Japanese Patent Office (07-138135). The 07-138135 reference teaches a

5α-reductase inhibitor comprising a solvent and an extract of at least one kind of plant. The reference specifically describes the extract of *Lagerstroemia speciosa* as plant which may be used and describes using the extract to grow hair. The solvent is described as water or a hydrophilic organic solvent such as ethanol, methanol, or acetone. The reference teaches that when a hair-growth agent is compounded with the inhibitor, the composition exhibits a remarkable hair growing effect. Claim 8 would be inherently met by the reference, because colosolic acid is in the extract of *Lagerstroemia speciosa*. See: abstract. Therefore, the 07-138135 reference clearly anticipates instant claims 1, 4-6, 8, 10, and 22-23.

Claims 1, 4-6, 8, 10, 13-15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO **JP 07126143 A** based on the Derwent Abstract and the English translation of the Abstract and Disclosure provided by the Japanese Patent Office (07-126143). The 07-126143 reference describes a cosmetic for whitening the skin, which contains an extract of *Lagerstroemia speciosa*. The reference teaches using the extract to prepare conventional cosmetics such as lotions, creams, emulsions, and packs using known additives and carriers. Claim 8 would be inherently met

by the reference, because colosolic acid is in the extract of *Lagerstroemia speciosa*. See: abstract. Therefore, instant claims 1, 4-6, 8, 10, 13-15, and 16 are clearly anticipated by the 07-126143 reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO **JP 07126143 A** based on the Derwent Abstract and the English translation

of the Abstract and Disclosure provided by the Japanese Patent Office (07-126143) as applied to claims 1, 4-6, 8, 10, 13-15, and 16 above, and further in view of Soudant et al **5,916,579**.

The 07-126143 reference discloses a cosmetic for whitening the skin, which contains an extract of *Lagerstroemia speciosa*. The reference teaches using the extract to prepare conventional cosmetics such as lotions, creams, emulsions, and packs using known additives and carriers. See: abstract. However, the primary reference does not specifically teach the percentages of the extract of instant claims 2-3, the sunscreens of instant claim 7,or the vitamins and bioflavonoids of claim 9.

Soudant et al disclose a treatment and/or prevention of the problems of adiposity and compositions which may be used for combating it. The reference describes the need for a composition which may be applied topically because the other methods which have been proposed for treating adiposity involve surgical methods which are invasive, risky, and expensive. See: col. 1, line 58 – col. 2, line 35.

The compositions which may be in the form of lotions, emulsion, gels, creams, etc. are taught to contain conventional additives such as UV screening agents, thickening agents, alph-hydroxy acids, preservative

agents, and in general, all the excipients usually found in the field of Pharmacopoeia. Further, the secondary reference teaches that compositions may contain plant extracts in amounts which overlap those of instant claims 2-3. See: col. 4, line 19 – col. 5 line 29. Moreover, the secondary reference teaches applying the composition on a daily basis and in amounts which vary depending on the concentration and agents chosen. See: col. 5, lines 30-61.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the skin whitening cosmetic formulation comprising an extract of *Lagerstroemia speciosa* of 07-126143 by adding the amounts of plant extract and conventional cosmetic ingredients as taught by Soudant et al, because of the expectation of obtaining a skin treatment composition capable of being applied to the skin daily which would have therapeutic slimming and whitening capabilities.

Claims 1-6, 8, 10-12 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO **JP 07138135A** based on the Derwent Abstract and the English translation of the Abstract and Disclosure provided by the Japanese Patent

Office (07-138135) as applied to claims 1, 4-6, 8, 10, and 22-23 above and further in view of Abe et al **4,839,168**.

The 07-138135 reference teaches a 5α-reductase inhibitor comprising a solvent and an extract of at least one kind of plant. The primary reference specifically describes *Lagerstroemia speciosa* as a plant extract which may be used and using said extract to promote hair growth. The solvent is described as water or a hydrophilic organic solvent such as ethanol, methanol, or acetone. The reference teaches that when a hair-growth agent is compounded with the inhibitor, the composition exhibits a remarkable hair growing effect. See: abstract. The reference teaches that the various dosage forms may be prepared, however, the primary reference does not specifically teach the amount of crape myrtle extract as claimed in claims 2-3, 11-12, and 24.

Abe et al describe hair cosmetic compositions which comprise an extract obtained by a polar solvent extraction of a plant and a polypeptide compound. The secondary reference describes how such compounds are made into compositions such as shampoo, rinse, set lotion, hair spray, etc. and how these compositions impart good hairstyle retentivity and a good feeling of touch. See: abstract. Abe et al describe other ingredients which

may be used in the composition such as UV absorbers, antioxidants, preservatives pearling agents, lotionizing agents, and the like. See: col. 4, lines 56-66.

The secondary reference describes the plant extract used in an amount ranging from 0.001-10.0 weight percent of the total composition, therefore, meeting the specific amounts of extract as claimed instantly in claims 2-3, 11-12, and 24.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition and method of using said composition of 07-138135 by adding the specific amounts of the plant extract as taught by Abe et al, because of the expectation of obtaining a hair growth composition in a lotion form with the a plant extract in an amount which would have leave the hair feeling good to the touch.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1619

September 28, 2001

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
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